REMARKS

Upon entry of the present amendment, claims 16-43 will be pending in the case, claims 1-15 having been canceled and new claims 16-43 added. Support for the new claims can be found in the original claims and throughout the specification. For example, support for new claim 16 can be found in the specification at page 5, line 7, to page 8, line 16. Support for new claim 17 can be found in the specification at page 4, lines 10-11. Support for new claims 18 and 19 can be found in the specification at page 3, line 10. Support for new claim 20 can be found in the specification at page 3, line 14. Support for new claim 21-24 can be found in the specification at page 5, line 7, to page 8, line 16. Support for new claim 25 can be found in the specification at page 9, lines 25-28. Support for new claim 26 and 27 can be found in the specification at page 4, lines 4-6. Support for new claim 28 can be found at page 9, lines 10-12. Support for new claim 29 can be found at page 4, lines 10-11. Support for new claims 30 and 31 can be found at page 3, line 10. Support for new claim 32 can be found at page 3, line 14. Support for new claim 33 can be found at page 9, lines 10-15. Support for new claim 33 can be found at page 9, lines 10-15. Support for new claim 34 can be found at page 5, line 30, to page 6, line 29. Support for new claim 35 can be found at page 3, lines 32-34. Support for new claim 36 can be found at page 3, line 14. Support for new claim 37 can be found at page 9, lines 10-15. Support for new claim 38 can be found at page 5, line 30, to page 6, line 29. Support for new claim 39 can be found at page 4, lines 10-11. Support for new claims 40 and 41 can be found at page 3, line 10. Support for new claims 42 and 43 can be found at page 4, lines 4-6. No new matter has been added.

As an initial matter, Applicants note that the Office Action Summary at the first page of the Office Action mailed October 5, 2007 (the "Office Action") does not acknowledge the present application's claim for foreign priority under 35 U.S.C. § 119. As recited in the first paragraph of the application (added by preliminary amendment filed with the application on September 26, 2005), the present application is a National Stage of PCT/JP2004/004331, which claims the benefit of PCT/JP2003/03975 and Japanese Patent Application Serial No. 2003-110898. Foreign priority benefits were claimed in the Combined Declaration and Power of

Attorney filed with a Submission of Missing Requirements on May 25, 2006. Copies of the certified copies of the priority documents were presumably supplied to the U.S. Patent and Trademark Office from the International Bureau. Applicants respectfully request that Examiner explicitly acknowledge the claim for foreign priority by checking the appropriate boxes on the Office Action Summary.

Rejections under 35 U.S.C. § 101

At page 2 of the Office Action, claims 1-7 were rejected for being directed to non-statutory subject matter. According to the Office Action, "the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products," and "the claims as written do not particularly distinguish that the antibody is in any way manipulated from its natural state."

Applicants submit that there is no evidence whatsoever that anti-PepT1 antibodies ever existed as "naturally occurring products," and so they have no "natural state." However, this issue is moot, as claims 1-7 have been canceled and replaced with new antibody claims 16-23, all of which specify that the antibody is "isolated." Since naturally occurring antibodies are not "isolated," applicants submit that the antibodies encompassed by the present claims are patentable subject matter under 35 U.S.C. § 101.

Rejections under 35 U.S.C. § 102

Claims 1-15 were rejected as being anticipated by Basu et al. (Pharmaceutical Research, 15(2):338-342, 1998) or Basu et al. (Pharmaceutical Research, 19(9 Suppl):S-37, Abstract No. APQ 1137, 1996). The Examiner argues that the claims are inherently anticipated, stating: "[a]lthough the cited references do not specifically teach that the antibody is capable of inhibiting transport activity or of suppressing the growth of cancer cells… the claimed invention only requires contacting of the antibody with cells that express the peptide transporter." (Office Action at page 3). Claims 1-15 have been canceled, so the rejection is moot as to them. To the

extent that the rejection may be applied to any of the newly presented claims, Applicants traverse.

The Basu et al. (1996) abstract teaches methods for generating mouse anti-PepT1 polyclonal antibody sera and screening them against PepT1 peptides and cell membrane fractions using ELISA. No further use for the antibodies is proposed by this reference.

The other reference, Basu et al. (1998), employed what may have been the same mouse polyclonal antibodies "as biochemical and structural probes of the PepT1 transporter protein" (p. 338, col. 2, 1st full paragraph). The authors go on to explain their purpose:

> The tools developed in this research may be used to generate critical information about the precise isoform of the transporter protein and folding of the dipeptide transporter. Detection of cell surface exposure of putative extracellular loops would be of considerable interest in examining the predicted structure and the surface expression of PepT1.

In the course of their experiments, Basu et al. (1998) carried out peptide ELISA, membrane ELISA, cell ELISA and immunoblot experiments with the polyclonal sera (p. 339, col. 1, through p. 340, col. 1).

All of the newly presented claims are limited to monoclonal or genetically engineered recombinant antibodies or fragments thereof (claims 16-23), compositions containing such antibodies or fragments thereof (claims 25-27), methods of using such antibodies or fragments thereof (claims 28-43), or diabodies (claim 24). Since the anti-PepT1 antibodies of Basu et al. (1996) and Basu et al. (1998) are polyclonal mouse antibodies, i.e., a mixture of many different antibodies, some of which bind to the antigen of interest but most of which do not, they would not meet the independent claim 16 criterion "a monoclonal or genetically engineered antibody or antigen-binding fragment thereof," nor the independent claim 24 criterion "a diabody". Furthermore, independent claims 16 and 24 both require that the antibody inhibit peptide uptake into a cell expressing the peptide transporter, an activity that is nowhere disclosed in Basu et al. and that is not necessarily present in all antibodies that happen to bind to a peptide transporter. Thus, for at least these reasons, all of the presently pending claims 16-43 are novel over the cited art.

Applicants note that the dependent claims contain additional limitations that further distinguish over the Basu et al. references. For example, claims 22, 34, and 38 require that the antibody be humanized or chimeric. Claim 23 requires that the antibody be bispecific. Claim 25 requires the presence of a pharmaceutically acceptable carrier, and also that the antibody or fragment thereof inhibit the growth of a cell. Claims 26, 27, 42, and 43 specify that the cell is a cancer cell or a pancreatic cancer cell. Claim 33 requires that the method of claim 28 be carried out *in vivo*; claim 37 similarly limits the method of claim 35. None of this is disclosed or inherent in either Basu et al. publication.

Accordingly, none of the present claims is anticipated by either Basu et al. reference. Withdrawal of the rejection is respectfully requested.

Applicants also point out for the record that there would have been no reason, based on the Basu et al. publications, to alter the teachings of Basu et al. and make an antibody or diabody of the invention, as this would have been of no advantage for the purely experimental purposes disclosed by Basu et al. (1998), i.e., as "biochemical and structural probes of the PepT1 transporter protein" (page 338, column 2, first full paragraph). In fact, Basu et al. (1998) teaches away from the idea of substituting monoclonal antibodies for their purposes, as "monoclonal antibodies recognize peptides in a specific conformation and therefore, may not necessarily recognize the transporter protein in its native conformation" (page 338, column 1). Furthermore, even if one were to generate anti-PepT1 monoclonal antibodies, there is no reason to suppose they would meet the functional criteria set out in the present claims.

Double patenting rejection in view of copending Application No. 10/497,900

Claims 1-15 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/497,900. These provisionally rejected claims are canceled, so the rejection is moot as to them. Since examination is ongoing in both applications and the final scope of the claims of either is not yet known, applicants request that the Examiner allow them to respond to this provisional rejection at a later date.

The Petition for Extension of Time fee in the amount of $460 and the fee of $400 for excess claims are being paid concurrently on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 14875-152US1.

Respectfully submitted,

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